ISRCTN34931928 https://doi.org/10.1186/ISRCTN34931928

The effects of homocysteine-lowering vitamin supplementation on migraine disability

Submission date	Recruitment status	[ ] Prospectively registered
29/11/2007	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
18/12/2007	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
18/12/2007	Nervous System Diseases	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Study objectives
Does vitamin therapy including folic acid reduce homocysteine and migraine disability, and is the effect dependent on MTHFR genotype?

Ethics approval required
Old ethics approval format

Ethics approval(s)
The study was approved by the Griffith University Ethics Committee on 11 November 2005 (ref: 3425)

Study design
Randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Migraine with aura

Interventions
Daily B vitamin (B6, B9, B12) therapy vs placebo for 6 months

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Migraine disability, as measured using the Migraine Disability Assessment (MIDAS) score at baseline and 6 months.

Secondary outcome measures
1. Migraine frequency. Duration of follow-up: 6 months
2. Migraine pain: MIDAS pain score 1-10 (10 = most severe) at baseline and 6 months

Overall study start date
30/11/2006

Completion date
30/11/2007

Eligibility

Key inclusion criteria
1. Current diagnosis of regular migraine with aura attacks
2. >18 and <70 years old

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
60

Key exclusion criteria
1. Co-morbid vascular or neuropsychiatric disease
2. Pregnant
3. Currently taking B vitamins

Date of first enrolment
30/11/2006

Date of final enrolment
30/11/2007

Locations

Countries of recruitment
Australia

Study participating centre
Griffith University
Gold Coast
Australia
9726

Sponsor information

Organisation
Griffith University (Australia)

Sponsor details
c/o Prof Lyn Griffiths
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Sponsor type
University/education

ROR
https://ror.org/02sc3r913

Funder(s)

Funder type
Research organisation

Funder Name
Brain Foundation of Australia

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration